Office Action Summary	Application No.	Applicant(s)
	10/575,640	T LEM ET AL.
	Examiner	Art Unit
	MARIANNE DIBRINO	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11 and 19-45* is/are pending in the application.

4a) Of the above claim(s) *9,10 and 19-41* is/are withdrawn from consideration.

5)☒ Claim(s) *42-45* is/are allowed.

6)☒ Claim(s) *1,3-8, 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☐ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and response filed 6/13/11 is acknowledged and has been entered.

2. Applicant is reminded of Applicant's election with traverse of Group I and species of SEQ ID NO: 12, which is comprised of SEQ ID NO: 4 present at amino acid residues 599-653 of SEQ ID NO: 12 that encodes an HLA class I molecule transmembrane and cytoplasmic regions, and SEQ ID NO: 10 which is human CMV phosphoprotein pp65 which is present at amino acid positions 36-596 of SEQ ID NO: 12, in the amendment and response filed 10/22/10.

Claims 1, 3-8, 11, 42 and newly added claims 43-45 are currently being examined.

3. Applicant's amendment filed 6/13/11 has overcome the prior rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

4. Applicant is reminded that for the purpose of prior art rejections, the filing date of the instant claims is deemed to be the filing date of PCT/EP04/11512, *i.e.,* 10/13/04, as a certified English language translation has not been provided for Germany 10347710.1.

5. Applicant's amendment filed 6/13/11 has overcome the prior rejection of record of claims 1 and 3-7 under 35 U.S.C. 102(b) as being anticipated by Rhode *et al* (J. Immunol. 1996, 157: 4885-4891, of record).

6. Applicant's amendment filed 6/13/11 has overcome the prior rejection of record of claims 1, 3-7 and 11 under 35 U.S.C. 103(a) as being unpatentable over Rhode *et al* (J. Immunol. 1996, 157: 4885-4891, of record) in view of US 20020110566 A1.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3-7 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/25054 A1 (IDS reference).

It is noted by the Examiner that the instant specification discloses that "derived" indicates that a sequence is present in the object from which it is derived, such as the object being a molecule (see in particular, the paragraph spanning pages 24-25).

WO 94/25054 A1 teaches a recombinant protein which is an MHC class I heavy chain wherein the alpha 1 and alpha 2 domains that form an antigen binding domain of the MHC molecule are substituted with a target amino acid sequence against which it is desired to induce an immune response (*i.e.*, an antigen), and said protein includes a leader sequence, transmembrane and cytoplasmic regions. WO 94/25054 A1 further teaches a vaccine comprising said protein, *i.e.,* a pharmaceutical composition comprising the protein and a pharmaceutically acceptable carrier as recited in instant claim 11 (see entire reference, especially page 13 at lines 5-9 and claims).

Note that instant claim 1 recites the open transitional phrase "comprising" that renders the claim open to other non-recited components.

Claim 7 is included in this rejection because the claim merely recites the "arrangement of segments" but does not recite that the listed segments are directly contiguous with one another in the recited order.

Applicant's arguments have been fully considered but are not persuasive.

Applicant's said arguments are of record on pages 9-10 of Applicant's amendment and response filed 6/13/11.

However, although the art reference at the locations cited by Applicant (page 7, lines 5-10 and page 7, line 24 to page 8, line 3) teaches that the protein should essentially include certain components and in one embodiment this includes an amino acid sequence which mediates binding of MHC class I to CD8 or MHC class II to CD4, the example cited in the instant rejection lacks the alpha 1 and alpha 2 domains that form an antigen binding domain of the MHC molecule. The disclosure in the instant specification that defines "MHC class I binding domain" is non-limitive for the exclusion of regions other than alpha 1 and alpha 2 from the construct of the invention (*i.e.,* the specification discloses at [0057] "The term "MHC class I binding domain" relates to the region of an MHC class I molecule or of an MHC class I chain which is necessary for binding to an antigenic peptide. An MHC class I binding domain is formed mainly by the alpha 1 and alpha 2 domains of the MHC class I alpha chain. Although the alpha 3 domain of the alpha chain and beta 2-microglubulin does not represent essential parts of the binding domain, they are presumably important for stabilizing the overall structure of the MHC class I molecule and therefore the term "MHC class I binding domain" preferably includes these regions." An MHC class I binding domain can also be essentially defined as the extracellular domain of an MHC I class I molecule, distinguishing it from the transmembrane and cytoplasmic regions."

The art fusion protein does not comprise the extracellular domain of an MHC class I molecule.

Applicant's further argument that the art reference is speculative and lacks enablement because it does not prove the capability of the fusion proteins to induce an immune response against the antigenic peptide (*i.e.*, the target amino acid sequence) is off-point. The reference is not required to prove efficacy. A prior art reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention; "proof of efficacy is not required for a prior art reference to be enabling for the purposes of anticipation. Impax Labs, Inc. v. Aventis Pharm. Inc., 468 F.3d 1366, 1383, 81 USPQ2d 1001, 1013 (Fed. Cir. 2006). See also MPEP 2122. In addition, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

9. Applicant is reminded that SEQ ID NO: 12 is free of the art.

10. Applicant's amendment filed 6/13/11 has overcome the prior objection of record of claim 42

11. Claims 42-45 are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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